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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/552,705	04/19/2000	Shiuan Chen	2124-311	4317
6449	7590 07/30/2002	•		:
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800			EXAMINER	
			FRONDA, CHRISTIAN L	
WASHINGTON, DC 20005		•	ADTIBUT	PAREN 180 0000
		i i	ART UNIT	PAPER NUMBER
		ŧ	1652	
			DATE MAILED: 07/30/2002	15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. **09/552,705**

Applicant(s)

Chen et al.

Examiner

Christian L. Fronda

Art Unit **1652**



Pariod	The MAILING DATE of this communication appears for Reply	on the cover sheet with the corre	spondence address
A SH THE	HORTENED STATUTORY PERIOD FOR REPLY IS SET MAILING DATE OF THIS COMMUNICATION. sions of time may be available under the provisions of 37 CFR 1.136 (a). In a date of this communication.		
- If the - If NO - Failure - Any r	g date of this communication. period for reply specified above is less than thirty (30) days, a reply within a period for reply is specified above, the maximum statutory period will apply to reply within the set or extended period for reply will, by statute, cause a eply received by the Office later than three months after the mailing date of dipatent term adjustment. See 37 CFR 1.704(b).	the statutory minimum of thirty (30) days will be and will expire SIX (6) MONTHS from the mails the application to become ARANDONED (25.1).	pe considered timely. Ing date of this communication.
Status	,		
1) 🗌	Responsive to communication(s) filed on		
2a) 💢		tion is non-final.	
3) 🗆	Since this application is in condition for allowance closed in accordance with the practice under <i>Ex pa</i>	except for formal matters, prose orte Quayle, 1935 C.D. 11; 453	ecution as to the merits is O.G. 213.
Disposi	tion of Claims	, , ,	5.2.2.6.
4) 💢	Claim(s) 44-51 and 53-55	is/are	e pending in the application.
4	4a) Of the above, claim(s)		
	Claim(s)		
6) 💢	Claim(s) <u>44-51 and 53-55</u>		
7) 🗆	Claim(s)		is/are objected to.
8) 🗌	Claims	are subject to restric	ction and/or election requirement.
Applica	tion Papers		
9) 🗆	The specification is objected to by the Examiner.		
10)	The drawing(s) filed on is/are	a) □ accepted or b) □ objecte	d to by the Examiner.
	Applicant may not request that any objection to the d	rawing(s) be held in abeyance. See	e 37 CFR 1.85(a).
11)	The proposed drawing correction filed on	is: a)□ approved	b) \square disapproved by the Examiner.
10\	If approved, corrected drawings are required in reply		
12) 📙	The oath or declaration is objected to by the Exami	ner.	
	under 35 U.S.C. §§ 119 and 120		
.o,⊡ a)□	Acknowledgement is made of a claim for foreign probability \square All b) \square Some * c) \square None of:	flority under 35 U.S.C. § 119(a)-	-(d) or (f).
	1. Certified copies of the priority documents hav	a haan raasiyad	
:	2. Certified copies of the priority documents have		_
;	3. Copies of the certified copies of the priority do		
	application from the International Burea se the attached detailed Office action for a list of the	30 (PCT Rule 17.2(a))	tilis National Stage
	Acknowledgement is made of a claim for domestic		e).
a) [_			- ,
15)∐	Acknowledgement is made of a claim for domestic	priority under 35 U.S.C. §§ 120	and/or 121.
ttachme	ent(s)		
	ice of References Cited (PTO-892)	4) Interview Summary (PTO-413) Paper N	
	ice of Draftsperson's Patent Drawing Review (PTO-948) rmation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal Patent Application (F	PTO-152)
		6) Other:	

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DETAILED ACTION

- 1. In the <u>AMENDMENT</u> dated 5/10/02 (paper no. 14), Applicants have amended claims 53 and 55.
- 2. Claims 44-51 and 53-55 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 101

- 3. 35 U.S.C. 101 reads as follows:
 - Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
- 4. Claims 44-51 and 53-55 are again rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Applicants' arguments filed 5/10/02 (Paper No. 14) have been fully considered but they are not persuasive. Applicants' position is that the claims of the invention are not drawn to the disclosed nuclear receptor co-regulatory protein itself but to an assay method. The Examiner disagrees.

The specification does not specifically disclose the specific function of the nuclear receptor co-regulatory protein comprising SEQ ID NOs: 5, 8, or 9 or its relationship to any disease. It appears that the main utility of the protein is to carry out further research to identify the biological function and possible diseases associated with the nuclear receptor co-regulatory protein. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 6. Claims 44-51 and 53-55 are again rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above in the rejection of claims 44-51 and 53-55 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.
- 7. Claims 44-51 and 53-55 are again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims encompass any protein of any amino acid sequence which comprises SEQ ID NO: 5, 8, or 9. The specification discloses that PNRC (proline-rich nuclear receptor coregulatory protein) has an amino acid sequence of 327 amino acid residues (SEQ ID NO: 8). The amino acid sequence of SEQ ID NO: 5 which consists of seven amino acid residues was identified as a binding motif in the disclosed PNRC having the amino acid sequence of SEQ ID NO: 8. The amino acid sequence of SEQ ID NO: 9 is disclosed as consisting of 23 amino acid residues which comprises SEQ ID NO: 5. However, the specification does not provide a written description of any protein comprising SEQ ID NO: 5, 8, or 9 because the specific amino acid sequence that is N-terminal and C-terminal to SEQ ID NO: 5, 8, or 9 has not been described. The specification does not provide any structural characteristics or properties for the protein other than comprising SEQ ID NO: 5, 8, or 9 for which no predictability of structure is apparent. Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Conclusion

- 8. No claim is allowed.
- 9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

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MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

SUPERVISORY PATENT EXAMINER TECHNOLOGY USHIER 1303

PONNATHAPU ACHUS MURTHY